



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

John

3/16/04

MAR 15 2004

Dr. Tibor Balint
Chief Veterinary Officer
Ministry of Agriculture and Regional Development
Animal Health and Food Control Department
H-1860
Budapest 55
Hungary

Dear Dr. Balint:

The Food Safety and Inspection Service has completed an enforcement audit of Hungary's meat inspection system. The audit was conducted from October 15 through November 5, 2003. Comments from Hungary have been included in the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by facsimile at 202-690-4040, or by email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Robert Curtis, Minister Counselor, US Embassy, Vienna

Mihaly Korintus, Agricultural Counselor, Embassy of the Republic of Hungary

James Dever, FAS Area Officer

Dave Young, ITP, FAS

Amy Winton, State Department

Linda Swacina, Deputy Administrator, FSIS

Karen Stuck, Assistant Administrator, OIA

Donald Smart, Director, Review Staff

Sally Stratmoen, Director, IES, OIA

Clark Danford, Director, IEPS, OIA

Mary Stanley, Director, IID, OIA

Nancy Goodwin, IES, OIA

Country File—Hungary Oct03 Audit

FINAL

MAR 1 2004

FINAL REPORT OF AN ENFORCEMENT AUDIT CARRIED OUT
IN HUNGARY COVERING
HUNGARY'S MEAT INSPECTION SYSTEM
OCTOBER 15 THROUGH NOVEMBER 5, 2003

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AHFCD	Animal Health and Food Control Department
AHFCS	Animal Health and Food Control Station
CCA	Central Competent Authority, Animal Health and Food Control Department, Ministry of Agriculture and Regional Development
FSIS	Food Safety and Inspection Service
MARD	Ministry of Agriculture and Regional Development
NFII	National Food Investigation Institute
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

1. INTRODUCTION

The enforcement audit took place in Hungary from October 15 through November 5, 2003.

An opening meeting was held on October 15, 2003, in Budapest, Hungary, with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objective and scope of the audit, the itinerary of each of the four auditors, and requested additional information needed to complete the audit of Hungary's meat inspection system. Information was requested concerning Hungary's training programs, enforcement activities, and bio-terrorism preparedness.

Each auditor was accompanied during the entire audit by representatives from the CCA, the Food Safety Unit (FSU) of the Animal Health and Food Control Department (AHFCD), a County Animal Health and Food Control Station, and/or the National Food Investigation Institute (NFII).

2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit. The objective of the audit was to evaluate the equivalence of Hungary's meat inspection system and the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: headquarters offices of the CCA, FSU, and NFII; seven County Animal Health and Food Control Station offices; six branch laboratories of the District central laboratories; the national reference laboratory for microbiology in Budapest; and seven establishments that were certified to produce and export product to the United States.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	County	7	Supervise Certified Establishments
Laboratories (all government)		6	
Meat Slaughter/Processing Establishments		6	
Meat Processing Establishments		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with headquarters and county officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or county offices. The third part involved on-site visits

to seven establishments: six slaughter/processing establishments and one processing establishment. The fourth part involved visits to six government laboratories involved in applicable microbiological testing.

Program effectiveness determinations of Hungary's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Points (HACCP) programs and testing programs for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including testing programs for *Salmonella*. Hungary's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors also assessed how inspection services are carried out by Hungary and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the lead auditor explained that Hungary's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Hungary. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, species verification, and the requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella* species.

Equivalence determinations are those that have been made by FSIS for Hungary under provisions of the Sanitary/Phytosanitary Agreement. There has been an equivalence determination, for Hungary, that generic *E. coli* samples can be analyzed in government laboratories.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction (PR)/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/oppde/far/index.htm.

Summary of February 2002 Audit Findings:

- No warm water in the locker room in one establishment.
- Windows in the locker room not closed to exclude pests in one establishment.
- Knife sanitizers not at proper temperature in one establishment.
- Cross contamination on finished carcasses due to dirty plastic flap contacting carcasses in one establishment.
- Condensation dripping in the carcass cooler, but not on the carcasses, in one establishment.
- Plastic product containers not identified for edible or inedible product in one establishment.

All of the above deficiencies were corrected before the February/March 2003 audit, with the exception of the observations involving dripping condensation and sanitizer temperatures.

Summary of February/March 2003 Audit Findings:

- SSOP preventative actions inadequately documented in six of seven establishments.
- SSOP verification procedures inadequately documented in all seven establishments.
- Person responsible for SSOP program not indicated in one of seven establishments.
- Inadequate documentation of monitoring for fecal contamination in one of six slaughter establishments.
- All three categories of hazards not addressed in the HACCP plans in five of seven establishments.
- HACCP plan verification and/or validation inadequately addressed in the HACCP plans in four of seven establishments.
- HACCP corrective/preventative actions inadequately addressed and/or documented in four of seven establishments.
- HACCP plan critical limits not documented properly in two of seven establishments.
- HACCP plan CCP documentation incorrect in four of seven establishments.
- HACCP plan pre-shipment review inadequate in two of seven establishments.
- Generic *E. coli* sampling inadequate in two of six slaughter establishments.
- Sanitary operations inadequate in four of seven establishments due to product residues/pieces, potentially insanitary paper towels, ingesta, sanitizer temperatures, and dripping condensation.
- Inadequate pest controls in three of seven establishments due to incorrectly sealed doors to the outside.
- Inadequate enforcement of FSIS requirements in four of seven establishments.
- Notices-of-intent-to-delist were issued to two of seven establishments.

All of the above deficiencies were corrected before the current October/November 2003 audit, with the exception of inadequate closure of excessive gaps observed on the sides of an outside door in one establishment.

6. MAIN FINDINGS

6.1 Government Oversight

Hungary's AHFCD is accountable to the Ministry of Agriculture and Regional Development (MARD) at the national headquarters in Budapest, Hungary. The CCA is the AHFCD and has the ultimate control over the production of food products derived from animals. The direct supervision and enforcement of FSIS requirements within Hungary's meat inspection system is provided by the National Food Investigation Institute (NFII) and the County Animal Health and Food Control Station (County Station) within MARD. The Food Safety Unit is responsible for the laws and decrees that are in place and establish the necessary controls for food hygiene, food quality, residues, food-processing, slaughter operations, and feed.

NFII performs audits in export establishments twice a year. The County Station performs monthly supervisory visits to certified establishments. FSU only visits establishments if there are significant problems identified by the NFII or by foreign auditors. The County Stations are the first line of supervision within the AHFCD for certified establishments eligible to export to the United States.

There are twenty county offices that have control over the meat establishments within their jurisdiction. Seven of these counties are responsible for the seven (one each) U.S. certified establishments. Each applicable County Station is responsible for four to six District Animal Health and Food Control Stations servicing and supervising non-certified establishments and other facilities. Each certified establishment has a head veterinarian who is in charge of the local inspection station at the establishment and receives direction directly from the County Station. The head veterinarian typically has one or more veterinarians and lay inspectors that perform inspection activities under his or her direction and supervision.

6.1.1 CCA Control Systems

As indicated earlier, the AHFCD of MARD has ultimate control over the slaughtering of livestock and the production of meat products and delegates responsibility for food safety investigations, imports, exports, and personnel training programs to the NFII. The Director of each County Station is directly answerable to the Director of AHFCD, the Chief Veterinary Officer (CVO) and liaison with FSIS. County Station Directors are responsible for all inspection activities within their counties, including the central county laboratories.

Consequently, each county office is responsible for carrying out mandates from the FSU and the AHFCD, most of the training of local veterinarians and inspectors, and the hiring, firing, and performance of inspection and other county personnel. Depending on directions from the AHFCD, the FSU, NFII, and/or the County Station will assist in or conduct labeling, fraud, contamination, and other investigations. Inspection personnel in each establishment control, on a daily basis, the slaughter of livestock and/or processing of meat products, respectively, within each certified establishment.

6.1.1 Ultimate Control and Supervision

The NFII in Budapest, Hungary is the fact-finding arm of the Director of AHFCD, who is ultimately responsible for the operational controls and supervision of certified establishments. County Station veterinarians perform the day-to-day supervision and management of certified establishments. In most cases, the Chief of the Food Hygiene Department of each County Station performs the monthly supervisory visits required by FSIS. The Chief, as well as an industry representative, and the veterinarian in charge of the government station at the establishment sign the supervisory report. The Director of the County Station typically performs one or two monthly reviews with and/or without the Chief of the Food Hygiene Department and adds his/her name to the signatures on the report generated from the visit. In addition, the twice a year audits by representatives from the NFII involve document reviews at the County Station and at each certified establishment. They also involve a visual review of inspection and establishment activities, procedures, and effectiveness.

6.1.2 Assignment of Competent, Qualified Inspectors

The County Animal Health and Food Control Stations are responsible for the selection, hiring, and training of inspectors within their jurisdiction. Veterinarians receive specialized training during their veterinary education. Lay inspectors who have graduated from secondary school must attend four years of specialized education corresponding to a high school education in the United States. Veterinarians receive additional training and new information through periodic MARD and County training sessions. County veterinarian-specialists attending MARD training sessions are expected to pass on this training to the applicable and appropriate veterinarians in their county, including the veterinarians in charge of the stations in export establishments.

The veterinarians in charge of establishment stations are then expected to pass on this information to the other veterinarians and lay inspectors working at their local inspection stations (government offices within establishments). Monthly supervisory visits and twice a year NFII audits are meant to ensure that new information secured from the training sessions is properly applied to establishment and inspection activities and procedures. This assurance is, however, not specifically documented in either the NFII or the monthly supervisory reports.

Inspector and veterinarian competence is achieved through the above supervisory visits and audits. Since 2001, annual performance evaluations are performed on all government employees in AHFCD, although the exact nature and content of the evaluations is still under development. To date, performance evaluations are primarily used to determine the salary level of an employee. They are not normally used in the selection process for a promotion or job change. Veterinarians pursue advancement, job changes, and additional expertise through the successful completion of specialized coursework in such areas as food hygiene, food quality control, animal husbandry, and administration. This specialized coursework, depending on the subject, takes from one week to two years to complete. An exam must be taken and passed at the end of each course.

6.1.3 Authority and Responsibility to Enforce the Laws

The authority and responsibility of enforcing applicable laws and regulations are vested in the Food Safety Unit of the AHFCD and delegated to the County Stations for certified export establishments. The County Station delegates this authority and responsibility to the District Stations for non-certified establishments and facilities and to the veterinarians in charge of certified establishment stations. Deficiencies that are pointed out during an NFII audit or during a monthly supervisory visit are resolved through the actions and subsequent letter by the veterinarian in charge of the government office in the export establishment. However, there is no apparent documentation that NFII, the County Station, or any other part of MARD has verified the appropriate resolution of the noted deficiencies. This weakness, along with possible weaknesses in relaying information received at training sessions to field stations, may have contributed to the delisting of one establishment during this audit.

6.1.4 Adequate Administrative and Technical Support

Each level of administration and control of the AHFCD has adequate administrative and technical assets to enable it to carry out its responsibilities. New FSIS or other instructions, requirements, and regulations are sent, as needed, to Country Stations and local establishment stations. If urgent, the information is sent in English, as received by the Director (CVO) of AHFCD, and followed by an official translation from the FSU. If sent in English, every Country Station has a qualified veterinary food hygienist who can translate the FSIS document and distribute it to the applicable establishment representatives, County veterinarians and establishment stations as soon as possible. Any subsequent official translation sent from the FSU in Budapest is compared to the County translation and distributed, as needed, along with a notice of the differences noted between the two translations.

County Station Directors meet with NFII and AHFCD personnel once every two months to review policies, procedures, and instructions and to become more informed about new domestic and international export requirements. County Directors periodically meet with County veterinarians within the County, including those from the District Offices and local inspection stations, to discuss these issues and strengthen controls over county establishments and facilities.

Government employees can raise formal and informal questions at any time regarding new or established information received by headquarters and the County Station. The FSU of the AHFCD, MARD is informed, in writing, of all formal questions from the field and the answers provided by the County Station. Questions that cannot be answered by the County veterinarians are answered by the FSU in consultation with the NFII and the Director of the AHFCD, as needed. If a question comes from the establishment station, the answer is processed through the County office before it goes to the establishment station. The FSU ensures that responses that may affect other County Stations are distributed to all applicable County Stations. The County ensures that FSU and Country Station responses that affect other Districts or export establishment stations are distributed, as needed.

Technical and administrative support is also provided through training within the County and by NFII, MARD. The training is reasonably thorough and frequent, and has specifically included the requirements of the PR/HACCP programs since the last FSIS audit of Hungary. The PR/HACCP information that was provided at headquarters in September of 2003, was significantly detailed and was presented to the veterinarians who conduct the monthly supervisory visits. This information was presented in a train-the-trainer format. As stated earlier, these veterinarians were then expected to pass this information on to County Station personnel and to the export facilities. There is, however, no test or exam that needed to be passed to determine the knowledge retained by the trainees. This is also true of previous PR/HACCP training. Although NFII visits certified establishments twice a year, this weakness in the system could contribute to the notable PR/HACCP deficiencies identified in two of the establishments that were audited and to the sanitation problems identified in the establishment that was decertified during this audit.

6.2 Headquarters Audit

The auditors conducted a review of inspection system documents at headquarters, at seven county offices, and seven establishment inspection offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses and procedures for residues and microbiological contaminants.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution.

No concerns arose as a result the examination of these documents at headquarters and at other locations.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of seven establishments. Six were slaughter/processing establishments and one was a processing establishment. One establishment was delisted by Hungary. This establishment was delisted due to deficiencies in operational sanitation and SSOP and HACCP implementation. In addition, one establishment received a 30-day NOID from Hungary's inspection officials. This establishment received an NOID due to deficiencies in the implementation of the HACCP, SSOP, and *Salmonella* testing programs.

Establishments receiving the 30-day notice may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was audited.

Specific deficiencies are noted in the attached individual establishment audit forms.

8. MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements. No residue documents were reviewed and no residue testing laboratories were visited during this audit. Microbiology laboratory audits focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and other aspects of laboratory quality assurance programs.

There are no private laboratories used to test samples for the presence of generic *E. coli* from product produced for export to the United States. The County branch laboratories are used for this purpose. Consequently, County branch laboratories were evaluated for compliance with the equivalence criteria established for generic *E. coli* testing under the FSIS PR/HACCP requirements.

The microbiology reference laboratory of the National Food Investigation Institute and five of the County branch laboratories were audited. The microbiology and residue laboratories in Budapest analyze field samples for the presence of *Listeria monocytogenes* and for species verification on products for export to the United States. The County branch laboratories analyze samples for generic *E. coli* and *Salmonella* species. The following deficiencies were observed:

- Five of the five laboratories conducting *Salmonella* analysis on ready-to-eat (RTE) products were testing 25 gram samples rather than the required 325 gram samples.
- All six branch laboratories were using the ISO 6579 analytical method to test for the presence of all *Salmonella* species. Although this method has been approved for other countries, Hungary has not submitted it to FSIS for an equivalence decision.
- The central laboratory for microbiology in Budapest was using a modification of the FSIS *Listeria monocytogenes* method that had been submitted to FSIS for prior approval. The modified method limits the effectiveness of screening for beta-hemolytic *Listeria monocytogenes* colonies, and may compromise the sensitivity of the method in some circumstances.
- One laboratory indicated that they maintain a reserve sample portion for possible re-testing in the event of a notable laboratory error affecting a positive result for pathogens. This was not an NFII policy and will be discontinued. This practice did not appear to have an impact on product destined for U.S. export.

As stated above, the Directors of the County Stations supervise the central county laboratories. The laboratories are also visited by the NFII and deficiencies are reported to the Director and the head of the central county laboratory. The head of the central county laboratory is responsible for the supervision of the local branch laboratories attached to particular export establishments. The analytical methods and laboratory procedures

provided by the NFII to all central county laboratories through the County Station, are passed on to the local branch laboratories by the head of the central county laboratory. Although NFII appears to periodically visit some branch laboratories, weaknesses in the multi-level transfer of critical information to the branch laboratories testing products for U.S. export may have contributed to the deficiencies noted in the microbiology laboratories during this audit.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess Hungary's meat inspection system. The first of these risk areas that the FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Hungary's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, Hungary's inspection system had controls in place for water potability records, back-siphonage prevention, separation of operations, temperature control, workspace, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. Basic SSOP requirements were met in all seven establishments and ongoing SSOP requirements were met in four of the seven establishments, with the following exceptions:

- Inadequate maintenance of ongoing requirements in three of seven establishments; specifically, isolated instances of inadequate documentation of product disposition, use of two program versions, and ineffective control of establishment sanitation (condensation and insanitary conveyor belts).

9.2 Sanitation

Each establishment was evaluated to determine if FSIS regulatory requirements for sanitation were met, according to the criteria employed in the United States domestic inspection program.

The following deficiencies were noted:

- Inadequate control of insects three of seven establishments.
- Inadequate operational sanitation in two of seven establishments; specifically, isolated instances of large gaps in an outside access door, inadequate lighting, flaking paint, carcass contact rod contacting floor, lack of paper towels and waste receptacles, insanitary conveyors, and cooler condensation.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditors determined that Hungary's inspection system had adequate controls in place. No deficiencies were observed in animal disease controls.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. There were no serious deficiencies found in the above controls.

The controls also include the implementation of HACCP systems in all establishments and the implementation of a generic *E. coli* testing program in slaughter establishments.

11.1 HACCP Implementation.

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the seven establishments. Five establishments had adequately implemented the HACCP requirements. The other two establishments had the following deficiencies:

- Verification frequencies were identical and instrument calibrations were too infrequent in one of seven establishments.
- Several critical control points had multiple critical limits in the other establishment.

11.2 Testing for Generic *E. coli*

Hungary has adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent measure:

- Hungary uses government laboratories to test for generic *E. coli*.

Six of the seven establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in four of the six slaughter establishments. The remaining two establishments had the following deficiencies:

- Use of the excision performance criteria to evaluate sponge sampling results in one of the six slaughter establishments.
- Improper positioning of the sample collection template at one sampling site in the other establishment.

11.2 Testing for *Listeria monocytogenes*

Three of the seven establishments audited were producing RTE products for export to the United States. In accordance with United States requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur. See Section 8 for the applicable deficiencies in this program.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors would normally review was Residue Controls. Only documentation at establishments was reviewed. No deficiencies were observed in the establishments in regard to residue documentation and adherence to the 2003 sampling schedule.

The NFII laboratory for residues in Budapest, Hungary is the reference laboratory for residues. This government laboratory was not audited during this audit.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*. The following general deficiency was noted:

- Inadequate enforcement of specific FSIS requirements in two of seven establishments.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

13.2 Testing for *Salmonella*

Hungary has adopted the FSIS requirements for testing for *Salmonella*.

All six of the slaughter establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* was properly conducted in five of the six slaughter establishments. The following deficiency was observed in the remaining establishment:

- Inadequate charting and analysis of *Salmonella* species test results in one of six establishments.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

Except for the following exceptions, it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

- Inadequate documentation indicating that the HACCP, SSOP, and generic *E. coli* and *Salmonella* species testing programs were sufficiently reviewed.
- Inadequate documentation of the verification of resolved deadlines and deficiencies by the County Station and NFII.
- Inadequate response by local inspection officials to indicated deficiencies in one of seven establishments.

13.5 Inspection System Controls

The CCA had controls in place, except as noted below, for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. The following deficiency was observed:

- Although separated by time, there was incomplete physical separation between the emergency slaughter area and the area for necropsy of dead-on-arrival (DOA) carcasses.

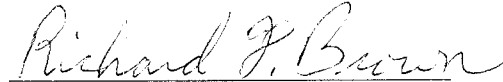
In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only livestock from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on November 5, 2003 in Budapest, Hungary, with the CCA. At this meeting, the preliminary findings and preliminary enforcement actions resulting from the audit were presented to inspection officials by the lead auditor.

The CCA understood and accepted the findings.

A handwritten signature in cursive script, reading "Richard F. Brown".

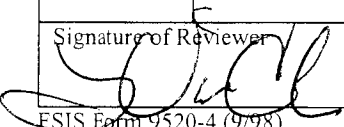
Richard F. Brown
Lead Auditor

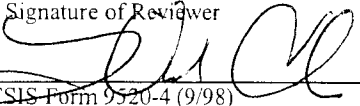
15. ATTACHMENTS TO THE AUDIT REPORT

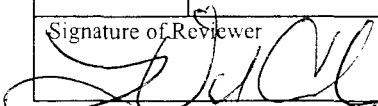
Individual Foreign Laboratory Audit Forms

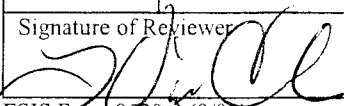
Individual Foreign Establishment Audit Forms

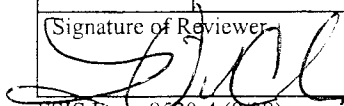
Foreign Country Response to the Draft Final Audit Report


U.S. Department of Agriculture Food Safety and Inspection Service Office of International Affairs FOREIGN COUNTRY LABORATORY REVIEW				Review Date 10/21/03		Name of Foreign Laboratory Kapuvar lab onsite at Est 10								
Foreign Government Agency Hungary			City and Country Kapuvar				Address of Laboratory Est 10							
Name of Reviewer L. Victor Cook			Name of Foreign Official Sas Bernard											
Residue/Micro. Code/Name →			Sal	Lm	Gen Ec									
Review Items ↓			Item # ↓											
Sampling Procedures	Sample Handling	01	A	O	A									
	Sampling Frequency	02	A	O	A									
	Timely Analyses	03	A	O	A									
	Compositing Procedures	04	A	O	A									
	Interpret Comp Data	05	O	O	O									
	Data Reporting	06	A	O	A									
Analytical Procedures	Acceptable Method	07	U	O	A									
	Correct Tissue(s)	08	A	O	A									
	Equipment Operation	09	A	O	A									
	Instrument Printouts	10	O	O	O									
Quality Assurance Procedures	Minimum Detection Levels	11	O	O	O									
	Recovery Frequency	12	O	O	O									
	Percent Recovery	13	O	O	O									
	Check Sample Frequency	14	A	O	A									
	All Analyst w/Check Samples	15	A	O	A									
	Corrective Actions	16	O	O	O									
	International Check Samples	17	O	O	O									
Previous Review(s)	Corrected Prior Deficiencies	18	O	O	O									
Other		19												
		20												
Signature of Reviewer 											Date 10/21/03			

U.S. Department of Agriculture Food Safety and Inspection Service Office of International Affairs FOREIGN COUNTRY LABORATORY REVIEW				Review Date 10/22/03		Name of Foreign Laboratory Gyongyos lab onsite at Est 24									
Foreign Government Agency Hungary			City and Country Gyongyos						Address of Laboratory Est 24						
Name of Reviewer L. Victor Cook			Name of Foreign Official Sas Bernard												
Residue/Micro. Code/Name →			Sal	Lm	Gen Ec										
Review Items ↓			Item # ↓												
Sampling Procedures	Sample Handling	01	A	O	A										
	Sampling Frequency	02	A	O	A										
	Timely Analyses	03	A	O	A										
	Compositing Procedures	04	A	O	A										
	Interpret Comp Data	05	O	O	O										
	Data Reporting	06	A	O	A										
Analytical Procedures	Acceptable Method	07	U	O	A										
	Correct Tissue(s)	08	A	O	A										
	Equipment Operation	09	A	O	A										
	Instrument Printouts	10	O	O	O										
Quality Assurance Procedures	Minimum Detection Levels	11	O	O	O										
	Recovery Frequency	12	O	O	O										
	Percent Recovery	13	O	O	O										
	Check Sample Frequency	14	A	O	A										
	All Analyst w/Check Samples	15	A	O	A										
	Corrective Actions	16	O	O	O										
	International Check Samples	17	O	O	O										
Previous Review(s)	Corrected Prior Deficiencies	18	O	O	O										
Other		19													
		20													
Signature of Reviewer 											Date 10/22/03				

U.S. Department of Agriculture Food Safety and Inspection Service Office of International Affairs FOREIGN COUNTRY LABORATORY REVIEW				Review Date 10/20/03		Name of Foreign Laboratory Papa lab onsite at Est 6							
Foreign Government Agency Hungary			City and Country Papa				Address of Laboratory Est 6						
Name of Reviewer L. Victor Cook			Name of Foreign Official Sas Bernard										
Residue/Micro. Code/Name →			Sal	Lm	Gen Ec								
Review Items ↓			Item # ↓										
Sampling Procedures	Sample Handling	01	A	O	A								
	Sampling Frequency	02	A	O	A								
	Timely Analyses	03	A	O	A								
	Compositing Procedures	04	A	O	A								
	Interpret Comp Data	05	O	O	O								
	Data Reporting	06	A	O	A								
Analytical Procedures	Acceptable Method	07	U	O	A								
	Correct Tissue(s)	08	A	O	A								
	Equipment Operation	09	A	O	A								
	Instrument Printouts	10	O	O	O								
Quality Assurance Procedures	Minimum Detection Levels	11	O	O	O								
	Recovery Frequency	12	O	O	O								
	Percent Recovery	13	O	O	O								
	Check Sample Frequency	14	A	O	A								
	All Analyst w/Check Samples	15	A	O	A								
	Corrective Actions	16	O	O	O								
	International Check Samples	17	O	O	O								
Previous Review(s)	Corrected Prior Deficiencies	18	O	O	O								
Other		19											
		20											
Signature of Reviewer 										Date 10/20/03			

U.S. Department of Agriculture Food Safety and Inspection Service Office of International Affairs FOREIGN COUNTRY LABORATORY REVIEW				Review Date 10/16/03		Name of Foreign Laboratory OEVI							
Foreign Government Agency Hungary		City and Country Budapest				Address of Laboratory Budapest							
Name of Reviewer L. Victor Cook		Name of Foreign Official Sas Bernard											
Residue/Micro. Code/Name →			Sal	Lm	Gen Ec	Spec ID							
Review Items ↓			Item # ↓										
Sampling Procedures	Sample Handling	01	O	A	O	A							
	Sampling Frequency	02	O	A	O	A							
	Timely Analyses	03	O	A	O	A							
	Compositing Procedures	04	O	A	O	A							
	Interpret Comp Data	05	O	O	O	O							
	Data Reporting	06	O	A	O	A							
Analytical Procedures	Acceptable Method	07	O	U	O	A							
	Correct Tissue(s)	08	O	A	O	A							
	Equipment Operation	09	O	A	O	A							
	Instrument Printouts	10	O	O	O	O							
Quality Assurance Procedures	Minimum Detection Levels	11	O	O	O	O							
	Recovery Frequency	12	O	O	O	O							
	Percent Recovery	13	O	O	O	O							
	Check Sample Frequency	14	O	A	O	A							
	All Analyst w/Check Samples	15	O	A	O	A							
	Corrective Actions	16	O	O	O	O							
	International Check Samples	17	O	O	O	O							
Previous Review(s)	Corrected Prior Deficiencies	18	O	O	O	O							
Other		19											
		20											
Signature of Reviewer 										Date 10/16/03			

U.S. Department of Agriculture Food Safety and Inspection Service Office of International Affairs FOREIGN COUNTRY LABORATORY REVIEW			Review Date 10/17/03			Name of Foreign Laboratory Szeged lab onsite at Est 7									
Foreign Government Agency Hungary		City and Country Szeged				Address of Laboratory Est 7									
Name of Reviewer L. Victor Cook		Name of Foreign Official Sas Bernard													
Residue/Micro. Code/Name →		Sal	Lm	Gen Ec											
Review Items ↓		Item # ↓													
Sampling Procedures	Sample Handling	01	A	O	A										
	Sampling Frequency	02	A	O	A										
	Timely Analyses	03	A	O	A										
	Compositing Procedures	04	A	O	A										
	Interpret Comp Data	05	O	O	O										
	Data Reporting	06	A	O	A										
Analytical Procedures	Acceptable Method	07	U	O	A										
	Correct Tissue(s)	08	A	O	A										
	Equipment Operation	09	A	O	A										
	Instrument Printouts	10	O	O	O										
Quality Assurance Procedures	Minimum Detection Levels	11	O	O	O										
	Recovery Frequency	12	O	O	O										
	Percent Recovery	13	O	O	O										
	Check Sample Frequency	14	A	O	A										
	All Analyst w/Check Samples	15	A	O	A										
	Corrective Actions	16	O	O	O										
	International Check Samples	17	O	O	O										
Previous Review(s)	Corrected Prior Deficiencies	18	O	O	O										
Other		19													
		20													
Signature of Reviewer 											Date 10/17/03				

U.S. Department of Agriculture Food Safety and Inspection Service Office of International Affairs FOREIGN COUNTRY LABORATORY REVIEW				Review Date 10/18/03		Name of Foreign Laboratory Kaposvar lab onsite at Est 62								
Foreign Government Agency Hungary			City and Country Kaposvar				Address of Laboratory Est 62							
Name of Reviewer L. Victor Cook			Name of Foreign Official Sas Bernard											
Residue/Micro. Code/Name →			Sal	Lm	Gen Ec									
Review Items ↓			Item # ↓											
Sampling Procedures	Sample Handling	01	A	O	A									
	Sampling Frequency	02	A	O	A									
	Timely Analyses	03	A	O	A									
	Compositing Procedures	04	A	O	A									
	Interpret Comp Data	05	O	O	O									
	Data Reporting	06	A	O	A									
Analytical Procedures	Acceptable Method	07	U	O	A									
	Correct Tissue(s)	08	A	O	A									
	Equipment Operation	09	A	O	A									
	Instrument Printouts	10	O	O	O									
Quality Assurance Procedures	Minimum Detection Levels	11	O	O	O									
	Recovery Frequency	12	O	O	O									
	Percent Recovery	13	O	O	O									
	Check Sample Frequency	14	A	O	A									
	All Analyst w/Check Samples	15	A	O	A									
	Corrective Actions	16	O	O	O									
	International Check Samples	17	O	O	O									
Previous Review(s)	Corrected Prior Deficiencies	18	O	O	O									
Other		19												
		20												
Signature of Reviewer 											Date 10/18/03			

United States Department of Agriculture
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Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION GYULAI HUSKOMBINAT RT. Gyula Ketegyhazi Ut. 3.	2. AUDIT DATE 10-17-03	3. ESTABLISHMENT NO. 5	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records	X	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions	X	59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PAPAI HUS RT. 8500 Papa, Kisfaludi ut. 2.	2. AUDIT DATE 10-21-03	3. ESTABLISHMENT NO. 6	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PICK SZEGED RT. SZEGED Szabadkai Ut.18.	2. AUDIT DATE 10 - 27 - 03	3. ESTABLISHMENT NO. 7	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION RINGA MEAT Co. KAPUVAR Cseresznyesor	2. AUDIT DATE 10-28-03	3. ESTABLISHMENT NO. 10	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION FALCOTRADE RT. Gyongyos, Szurdok part 1.	2. AUDIT DATE 10-16-03	3. ESTABLISHMENT NO. 24	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION KOMETA 99 KFT. Kaposvar, 7400 Pecs ut 67-69.	2. AUDIT DATE 10-01-03	3. ESTABLISHMENT NO. 62	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	X
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Pick Szeged Rt. Cegledi Telephely 2700 Cegled, Dohany ut. 30.	2. AUDIT DATE 10-30 - 03	3. ESTABLISHMENT NO. 147	4. NAME OF COUNTRY Hungary
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		



Ministry of Agriculture and Regional Development
Animal Health and Food Control Department

☒ H - 1860 Budapest 55., Pf.: 1.
☎ (36-1) 301-4000. Fax: (36-1) 302-0408.

HUNGARY

/2004.

Sally Stratmoen,
Director
United States Department of Agriculture (USDA)
Food Safety and Inspection Service (FSIS)
International Equivalence Staff
Office of International Affairs

January 26, 2004.

Washington D.C.

Dear Ms. Stratmoen,

Thank you very much for the Draft Final Report of the Audit conducted from October 15 through November 5, 2003. and you sent me on 11th of December. I would like to take the opportunity to provide comments within the required (60 days) time limit.

1. First of all I would like to inform you on the measures taken in the field of **laboratories**:

a/ Testing for Listeria monocytogenes (Lm)

Until the last audit, the central laboratory for microbiology (National Food Investigation Institute NFII) in Budapest was using a modification of the FSIS Lm method that had been submitted to FSIS for prior approval. In accordance with the relevant recommendation of Mr. Victor Cook, I am pleased to inform you that from December 2003 the laboratory for microbiology of NFII launched to use horse blood overlay agar to detect beta-haemolytic Lm colonies, which is in compliance with the USDA-FSIS method MLG 8.03.

b/ Testing for Salmonella

- After the audit the country branch laboratories were instructed to use 325 gram samples instead of 25 gram samples for Salmonella testing of lots to be exported to USA.
- Testing method for the presence of Salmonella species EN ISO 6579 will be submitted to FSIS for approval at the same time with this document (this method has been approved for other countries).

5. Establishment audit and corrective actions

a/ Establishment No. 6. (Pápai Hús Rt.)

Deficiency:

Several rail hook holders were observed to have loose rust on them that was not addressed during the pre-operational sanitation. The establishment management scheduled proper corrective action.

Corrective action:

The establishment has carried out a proper anti-rust treatment on the rail hook holders. Deficiency was checked by the Hungarian Inspection Service and found corrected.

b/ Establishment No. 7. (Pick Szeged Rt.)

Deficiency:

The screen over one ventilator in the hallway of the smokehouse area was missing. The establishment management scheduled installation.

Corrective action:

However little the risk was that insects might enter the hallway via the fan due to the heavy smoke in the hallway, the establishment has installed the screen required to prevent insects from entering.

Deficiency was checked by the Hungarian Inspection Service and found corrected.

c/ Establishment No. 10. (Ringa Húsipari Rt.)

Deficiencies:

- The establishment SSOP exists in two versions with different dates, making these documents difficult to evaluate. The establishment management will correct this deficiency.
- The template used at one of the E. coli carcass sampling sites was improperly positioned. The establishment management and inspection service will correct this for future sampling.

Corrective actions:

- The existing two versions were due to the fact that the establishment recently quit processing activity and due to the change of operator. An updated version of the SSOP has been presented to the inspection service that covers only those activities (slaughtering and boning) which are carried out in the plant.
- The designated employee who is responsible for E. coli carcass sampling has been properly instructed and trained for correctly positioning sampling sites by the IIC.

Deficiencies were checked by the Hungarian Inspection Service and found corrected.

g/ Establishment No. 62. (Kometa 99 Kft.)

This establishment was delisted during the audit by the Hungarian Inspection Service. Most of the deficiencies have already been eliminated but the establishment is still kept delisted.

6. Comments in relation to the previous audit (February/March 2003)

In the previous audit report written by Mr. Judd Giezentanner and referred to in the current draft final audit report, the auditor (Mr. Giezentanner) emphasizes that in each of the seven establishments there were deficiencies in describing *validation* and *verification* activities in the *SSOP plan*.

I would like to draw your attention to the fact that there are no such requirements for establishment verification and validation of the SSOP's in the Code of Federal Regulations (see: CFR § 416. 11-17.). Only inspection service is required to verify Sanitation SOP's.

I hope when you make your decision based upon the audit reports you will omit those facts that are not specified in the law and therefore they are not deficiencies.

I can assure you that all deficiencies mentioned above were checked and found corrected by the Hungarian Inspection Service.

I hope that, FSIS will find the measures taken by the establishments and the Hungarian Inspection Service satisfactory and they will contribute to resuming meat exports to USA.

Yours Sincerely,

Dr. Tibor Bálint
Chief Veterinary Officer